#### PATENT APPLICATION

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Docket No: Q105979

Kenya SHITARA et al.

Appln. No.: 10/575,261 Group Art Unit: 1644

Confirmation No.: 9631 Examiner: DAHLE, CHUN WU

Filed: April 10, 2006

For: FUSED PROTEIN COMPOSITION

## STATEMENT OF AVAILABILITY

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

We, KYOWA HAKKO KIRIN CO., LTD. of 1-6-1, Ohtemachi, Chiyoda-Ku, Tokyo, JAPAN 100-8185, declare and state that:

We are the Assignees of the entire right, title and interest of the invention described and claimed in the above-identified application, as evidenced by the Assignment recorded on March 13, 2009 at REEL 022396, FRAME 0508.

We agree that upon allowance and issuance of the above identified application into a United States Patent, restriction on availability of the following deposits will be irrevocably removed:

- (1) FERM BP-8499
- (2) FERM BP-8500
- (3) FERM BP-8503

## (1) transformant KC1194 derived from Chinese hamster ovary tissue-derived CHO cell line CHO/DG44

which is designated in the specification of the above-identified application and was deposited under the terms of the Budapest Treaty on September 30, 2003, as FERM BP-8499 in the International Patent Organism Depositary, National Institute of Advanced Industrial Science and Technology, Central 6, 1, Higashi 1-chome, Tsukuba-shi, Ibaraki, Japan.

# (2) transformant KC1198 derived from Chinese hamster ovary tissue-derived CHO cell line CHO/DG44

which is designated in the specification of the above-identified application and was deposited under the terms of the Budapest Treaty on September 30, 2003, as FERM BP-8500 in the International Patent Organism Depositary, National Institute of Advanced Industrial Science and Technology, Central 6, 1, Higashi 1-chome, Tsukuba-shi, Ibaraki, Japan.

## (3) transformant KC1200 derived from Chinese hamster ovary tissue-derived CHO cell line CHO/DG44

which is designated in the specification of the above-identified application and was deposited under the terms of the Budapest Treaty on October 3, 2003, as FERM BP-8503 in the International Patent Organism Depositary, National Institute of Advanced Industrial Science and Technology, Central 6, 1, Higashi 1-chome, Tsukuba-shi, Ibaraki, Japan.

We agree that the above-identified strains designated in the above identified application will be maintained for a period of 30 years or 5 years after the last request for the deposit, or for the effective life of any patent which issues on the above identified application, whichever is longer;

We agree that if the deposits become non-viable, they will be replaced; and

We also assure access to the deposits to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Respectfully submitted,

/Tu A. Phan/

Tu A. Phan, Ph.D. Registration No. 59,392

On behalf of: KYOWA HAKKO KIRIN CO., LTD.

SUGHRUE MION, PLLC Telephone: (202) 293-7060 Facsimile: (202) 293-7860

WASHINGTON OFFICE
65565
CUSTOMER NUMBER

Date: November 17, 2009

SUGHRUE (1)

# 3/ 8

#### 養式8(第7条第1項關係)

「特許学統上の微生物の寄託の国際的承認 に関するブタペスト条約」

下記園廠管託当局によって規則7.1に従い 発行される。 BUTAPEST TREATY OF THE INTERNATIONAL RECOGNITION OF THE BEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT
issued pursuant to Rule 7.1 by the INTERNATIONAL
DEPOSIT AUTHORITY identified at the bottom of this page.

## 原寄託についての受託証

氏名 (名称)

協和配酵工業株式会社 取締役社長 松田 譲 股

あて名

東京都平代田区大事町一丁目6番1号

Ą	1、微生物の設示		
1	(岩託者が付した職別のための表示)	(受託番号)	i
	KC1194	FERM BP- 08499	
	2. 科学的性質及び分類学上の位置		

1欄の微生物には、次の事項を記載した文章が総付されていた。

图 科学的性質

[2] 分類学上の位置

3. 受領及び受託

本製際寄託当局は、2003 年 9 月 30 日(原寄託日)に受領した1機の微生物を受託する。

4. 移管調求の受領

本国際客託当局は、年月田(原客託日)に受領した1機の微生物を受託した。

そして、年 月 日に原杏託によりプタベスト条約に基づく杏託への移管額求を登録した。

5. 陶際密託当局

名称 独立行政法人產案技術総合研究所 特許生物音託センター

International Patent Organism Depositary National Institute of Advanced Industrial Science and Technology

センター長 岡 修一

Dr.Svuichi Oka, Directo

あて名 日本園茨城県つくば市東1丁目1番地1 中央第6(郵便番号305-8566)

AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan

平成 15 年 (03) 9 月 30 日

SUGHRUE (1) :

# 4/ 8

(Translation)

INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

TO DEPOSITOR:

Name: KYOWA HAKKO KOGYO CO., LTD.
Representative: Yuzuru Matsuda

Address: 6-1, Chtemachi I-chome, Chiyoda-ku, Tokyo

#### I. IDENTIFICATION OF MICROORGANISM

Identification Reference Given by the Depositor: KC1194

Accession Number: FERM BP-8499

#### II. A SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC POSITION

The microorganism identified under I above was accompanied by a document stating the following item(s).

- A Scientific Property
- Taxonomic Position

#### III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above, which was received on September 30, 2003 (date of the original deposit).

### IV. RECEIPT OF REQUEST FOR TRANSFER

This International Depositary Authority received the microorganism under I above on (date of the original deposit), and received on a request for transfer from the original deposit to the deposit under the Budapest Treaty.

### V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: International Patent Organism Depositary

National Institute of Advanced Industrial Science and Technology

Representative: Syuichi Oka (sealed)
Dr. Syuichi Oka, Director

Address: AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi,

Ibaraki-ken 305-8566 Japan

Date: September 30, 2003

#### 賽式8(第7条第1項關係)

「特許学績上の微生物の寄託の国際的承認 に関するプタベスト条約:

下記靈際等託当局によって規則7.1に従い 発行される。 BUTAPEST TREATY OF THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE
RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT
issued pursuant to Rule 7.1 by the INTERNATIONAL

DEPOSIT AUTHORITY identified at the bottom of this page.

原寄託についての受託証

氏名 (名称)

協和醗酵工菜株式会社 取締役社長 松田 頸 殿

あて名 〒 100-8185 東京都千代田区大学町一丁目6番1号

1. 数生物の表示 (新計書が付した説別のための姿示) (受託券号) KCI198 FERM BP- 08500

2. 科学的性質及び分類学上の位置

1欄の微生物には、次の事項を記載した文章が添付されていた。

图 科学的性質

図 分類学上の位置

3. 受領及び受託

本国際等託当局は、2003年 9月 30日(原寄託日)に受領した1裸の微生物を受託する。

4. 終管開業の零部

本簡勝等託当席は、毎月日(順売計日)に受領した1機の微牛物を受託した。

そして、年 月 日に原書託によりブタベスト条約に基づく客託への移管請求を受領した。

5、國際客託当局

名称 独立行政法人商券技術総合研究所 特許生物客託センター

International Patent Organism Depositary

National Institute of Advanced Industrial Science and Technological

センター長 関修一

Dr.Syuichi Oka, Directa

あて名 日本国茨城県つくば市東1丁目1番地1 中央第6(郵便番号305-8566)

AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan

平成 15 年 (03) 9 月 30 日

SUGHRUE (1) :

# 8/ 8

(Translation)

INTERNATIONAL FORM

EUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

TO DEPOSITOR:

KYOWA HAKKO KOGYO CO., LTD. Name: Representative: Yuzuru Matsuda

6-1, Ohremachi 1-chome, Chivoda-ku, Tokvo Address:

I. IDENTIFICATION OF MICPOOPGANISM

Identification Reference Given by the Depositor: KC1198

Accession Number: FERM BP-8500

II. A SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC POSITION

The microorganism identified under I above was accompanied by a document stating the following item(s).

- A Scientific Property
- Taxonomic Position

III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above, which was received on September 30, 2003 (date of the original deposit).

IV. RECEIPT OF REQUEST FOR TRANSFER

This International Depositary Authority received the microorganism under I above on (date of the original deposit), and a request for transfer from the original received on deposit to the deposit under the Budapest Treaty.

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: International Patent Organism Depositary

National Institute of Advanced Industrial Science and Technology

Representative: Syuichi Oka (sealed)
Dr. Syuichi Oka, Director

Address: AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan

Date: September 30, 2003

SUGHRUE (1)

# 7/ 8

#### 膏式8(第7条第1項關係)

「特許手統上の微生物の客託の国際的承認 に関するプタベスト条約」

下記国際答託当局によって規則7.1に従い 発行される。

BUTAPEST TREATY OF THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7,1 by the INTERNATIONAL

DEPOSIT AUTHORITY identified at the bottom of this page.

原寄託についての受託証

氏名 (名称)

協和配酵工學株式会社 取締役社長 松田 醸 駿

あて名 ₹ 100-8185 東京都千代田区大手町一丁音6巻1号

1. 微生物の表示

(装託者が付した職別のための表示)

KC1200

PERM BP- 08503

(學話器母)

2. 科学的性質及び分類学上の位置

1欄の微生物には、次の事項を認載した文章が添付されていた。

图 科学的性質

☑ 分類学上の位置

3. 學簡及75學新

本国際告託当局は、2003年 10月 3日(原管託日)に受領した1機の微生物を受託する。

4. 移管請求の受領

本国際新託当局は、年月日(原寄託日)に受領した1欄の微生物を受託した。

そして、年月日に原寄託によりブタベスト条約に基づく寄託への移管請求を受領した。

5. 國際寄託甾周

名称 独立行政法人蓬敦技術総合研究所 特許生物寄託センター

International Patent Organism Depositary National Institute of Advanced Industrial Science and Technology

センター長

Dr.Syuichi Oka, Director

岡 体一

あて名 日本国茨城県つくば市東1丁目1番地1 中央第6(類便番号305-8568)

> AIST Tsukuba Central 6, 1-1, Higashi I-Chome Tsukuba-shi. Ibaraki-ken 305-8566 Japan

> > 平成 15 年 (03) 10 月 3 日

SUGHRUE (1) :

# 8/ 8

(Translation)

INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

TO DEPOSITOR:

KYOWA HAKKO KOGYO CO., LTD. Name: Representative: Yuzuru Matsuda

Address: S-1, Ohtemachi 1-chome, Chiyoda-ku, Tokyo

I. IDENTIFICATION OF MICROORGANISM

Identification Reference Given by the Depositor: KC1200

Accession Number: FERM BP-8503

II. A SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC POSITION

The microorganism identified under I above was accompanied by a document stating the following item(s).

A Scientific Property

Taxonomic Position

III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above, which was received on October 3, 2003 (date of the original deposit).

IV. RECEIPT OF REQUEST FOR TRANSFER

This International Depositary Authority received the microorganism under I above on (date of the original deposit), and received on a request for transfer from the original deposit to the deposit under the Budapest Treaty.

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: International Patent Organism Depositary

National Institute of Advanced Industrial Science and Technology

Representative: <u>Syuichi Oka (sealed)</u>
Dr. Syuichi Oka, Director

Address: AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi,

Ibaraki-ken 305-8566 Japan

Date: October 3, 2003